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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,753	03/04/2004	Tsutomu Fujimura	24997GUS0	5264
22850	7590	08/18/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER LEITH, PATRICIA A	
			ART UNIT 1655	PAPER NUMBER
			NOTIFICATION DATE 08/18/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

### Office Action Summary

**Application No.**

10/791,753

**Applicant(s)**

FUJIMURA, TSUTOMU

**Examiner**

Patricia Leith

**Art Unit**

1655

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5, 8, 9, 11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 6, 10, 12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-6 and 8-25 are pending in this application.

Claims 1-3, 5, 8, 9, 11 and 13 remain withdrawn from consideration on the merits at this time as these claims are specifically directed toward a non-elected invention.

Claims 4, 6, 10, 12 and 14-25 were examined on their merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 24 and 25 are each respectively dependent upon claim 4. Claim 4 is directed toward a method for treating aging of the skin in a subject. The only place in the Specification which teaches the ranges set forth in new claims 24 and 25 are with respect to the *in-vitro* fibroblast studies, and there is no indication in the Specification which the Examiner can construe which demonstrates that Applicants contemplated administration, to a subject, the newly claimed ranges of *Digenea simplex*.

With regard to application of the claimed product, the Specification teaches:

[0025] When any of the aforementioned plants is incorporated as an active ingredient into the present preventing/improving agent or the present expression enhancing agent, the amount of the plant as reduced to dry weight is preferably 0.00001 to 5 wt. %, more preferably 0.0001 to 3 wt. % of the agent. Meanwhile, when an extract of the plant is incorporated as an active ingredient, the amount of the extract as reduced to solid content is preferably 0.00001 to 5 wt. %, more preferably 0.0001 to 2 wt. % of the agent.

Hence, it appears that [0025] of the Specification provides the ranges which Applicants contemplated for administration to a subject, and not the newly claimed ranges of 0.00001% to 0.01% and 0.00001% to 0.0025.

Applicant is asked to either cancel the claims; amend the claims to exclude the New matter or alternatively, point to where in the Specification this information can be found in order to overcome this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6, 10, 12 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopes (US 5,942,478) in light of SigmaAldrich (1996)\*.

Lopes teaches microbiocidal and sanitizing soaps for topical administration to the skin (see entire reference and Abstract). More specifically, Lopes includes, as a 'skin-lubricating and skin-protecting agent' including 'agar-agar', see, for example, col. 2, lines 1-38 and more specifically, col. 2, line 27; see also claim 18 which specifically claims an a bactericidal and antimicrobial soap for topical use which contains agar-agar as the skin-lubricating/skin-protecting agent in an amount of 0.1 to 25% by weight of the composition). Claim 12 specifically claims the soap in a gel or a liquid form which meets the limitations of claims 10 and 17. It is noted that the recitation of agar-agar in claim 18 of Lopes for example, is an explicit description of an embodiment containing agar-agar. Markush-type language in claims is merely a means for Applicants to claim numerous embodiments without having to expressly write alternative embodiments in many, many independent claims. Hence, every alternative species present in the Markush group as claimed in Lopes is considered a specific, patentable embodiment.

SigmaAldrich teaches that *Digenea simplex* mucilage (an extract of *Digenea simplex*) is a polysaccharide complex also known as agar, agar-agar, gum agar and Gelose for example (see pp. 1-2). Therefore, the 'agar-agar' (a.k.a '*Digenea simplex* mucilage') of Lopes meets the description of a *Digenea simplex* extract.

Lopes does not explicitly teach wherein the amount of extract used (as reduced to dry weight) is 0.00001 to 5% based on the total amount of the agent, or wherein the agent is applied to the skin in an amount of from 0.01 to 10 mg/cm<sup>2</sup> or in an amount of

0.00001% wt. to 0.01% or 0.00001% to 0.002%. Lopes also does not explicitly state that agar-agar increases an expression level of Rho kinase or myosin light-chain kinase or increases force generated by skin non-muscular cells.

The ordinary artisan would have had a reasonable expectation that the method of Lopes would have carried out the function of 'increasing an expression level of Rho kinase or myosin light-chain kinase' or 'increases force generated by skin non-muscular cells' because the only step which achieves this requirement, as recited by the claims, is by contacting the skin with an extract of Digenea Simplex. Clearly, the composition of Lopes which includes agar-agar (Digenea Simplex) as a skin conditioning/lubricating would therefore be expected to fulfill these functional limitations absent evidence to the contrary:

"As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, *the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.*

It is clear that the amount of agar in the claims of Lopes overlaps with the claimed amount of extract which recites 0.00001 to 5%, i.e., Lopes teaches 0.1 to 25% thus rendering obvious this claimed amount range. Absent any showing of an unexpected results, ranges overlapping with those of Lopes are deemed to be values achieved upon routine experimentation, such experimentation being within the skill level of the ordinary artisan at the time the invention was made.

With regard to the amounts present in claims 24 and 25 which do not overlap with Lopes, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of *Digenea simplex* mucilage (agar-agar) because this component is an art-recognized result-effective variable which would have been routinely determined and optimized in the cosmetic art. While Applicants may argue that the Examiner is presenting a motivation for adjusting the percentage amount of *Digenea simplex* in the prior art to suit another use as claimed which is improper; the claims do not state that the treatment is for any specific use and hence, the 'treatment' as set forth in the claim may be directed toward treatment of dry skin or cleansing the skin which were purposes disclosed by Lopes.



Although the prior art does not specifically teach the measurements of the surface area to be treated, the ordinary artisan would have been motivated to vary the amount of product administered to the skin dependant on the amount of surface area in need of treatment in order to maximize efficacy of the cosmetic composition.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability...**if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

**...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants' arguments were fully considered, but were not found convincing to overcome the outstanding rejections.

First, as pointed out above, the claims are not specifically directed toward treatment of wrinkles or sagging skin; rather, the claims are directed toward treatment of aging skin, wherein the subject treated has wrinkles or sagging skin or loss of skin elasticity. Thus, the 'treatment' may be a cleansing and /or moisturizing treatment which is already provided by applying the product of Lopes. Thus, for purposes of examination of the claims under 112 First paragraph, as well as for prior art purposes, the claims are interpreted as not being directed toward a method for treating wrinkles, sagging skin or loss of skin elasticity; rather, the claims are directed toward a method for treating skin by administering to a patient having one of these conditions, a composition comprising an extract of *Digenea simplex*.

Applicants traverse the outstanding rejection in five categories. Specifically, they argue;

(1) That the prior art does not teach treating of skin which has wrinkles, sags and /or loss of skin elasticity (p. 8 and 9).

Applicants stress that the claimed invention is directed toward a method and not a composition (p. 9, Remarks); which is recognized by the Examiner and is rendered

obvious by the prior art teachings. The composition of Lopes is directed toward a moisturizing, cleansing product. Clearly the cleansing product is directed for general use which would include use by elderly persons having wrinkles, sagging and/or loss of skin elasticity. Since the product of Lopes was designed for the general public, an aging person having these conditions would have been motivated to have cleansed with the moisturizing cleansing compositions of Lopes.

Applicants argue that the lubrication properties of the cleansing composition of Lopes "does not describe that [it]...can treat the aging skin which has wrinkles" (p. 9, remarks). However, again, the claims are not directed toward treatment of wrinkles, sagging or loose skin; rather, they are broadly directed toward treating the skin. 'Treating' is very broad and can be directed toward treatment by cleansing or moisturizing which is the primary focus of the Lopes patent.

(2) That 'agar-agar' is different from *Digenea simplex*:

Applicants state that "agar is generally produced from small red algae belonging to the order Gelidiales which is different from [sic] the order Ceramiales to which *Digenea simplex* belongs" (p. 10, Remarks). However, Applicants' remarks and submitted publications do not negate the fact that *Digenea simplex* contains *Digenea simplex* mucilage which is the same as agar or agar-agar. While other types of algae may also produce agar, Sigma Aldrich makes clear that *Digenea simplex* mucilage is

agar, or 'agar-agar' and hence, is the same substance whether produced by *Digenea simplex* or another algae. Hence, Applicants' remarks and evidence are not found convincing to demonstrate that *Digenea simplex* mucilage is not the agar-agar of Lopes. To reiterate from the previous Office action, the claims are broadly directed toward any extract of *Digenea simplex*; hence, *Digenea simplex* mucilage which is obtained from *Digenea simplex*, fits the description of an extract of *Digenea simplex*.

(3) That the references do not describe an agent capable of increasing the force generated by skin non-muscular cells, wherein the skin non-muscular cells are skin fibroblasts. " (p. 11, Remarks).

However, Applicants' claims are broadly directed toward any extract of *Digenea simplex*. Since the prior art composition is the same composition of the claims, the composition is presumed to have the claimed characteristics unless it is demonstrated that the prior art product is not capable of producing the claimed effect.

(4) That the references do not describe an amount of 0.00001% to 0.01% or 0.00001% to 0.002% as required by claims 24-25 (p. 11, Remarks).

While it is true that the prior art did not specifically teach these ranges, as it is stated above under the rejection which takes into consideration Applicants' newly inserted percentage limitations; optimization of result effective variables is obvious

absent some showing of an unexpected result. Thus, it would have been obvious to modify the amount of agar-agar in the composition of Lopes to optimize moisturization capabilities of their cleansing/moisturizing composition.

(5) That one would not have been motivated to select a subject in need of treatment of wrinkles, sagging skin and/or loss of skin elasticity' (p. 11, Remarks).

However, respectfully, Applicants are arguing limitations which are not present in the claims. The claims do not require treatment of any particular condition. Nor do the claims require selection of a subject in need of any particular treatment. Hence, Applicants' arguments are not pertinent to the claimed invention. To reiterate from above, clearly the cleansing product of Lopes which contains agar-agar as a lubricating agent is directed for general use which would include use by elderly persons having wrinkles, sagging and/or loss of skin elasticity. Since the product of Lopes was designed for the general public, an aging person having these conditions would have been motivated to have cleansed with the moisturizing cleansing compositions of Lopes.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
Art Unit 1655

/Patricia Leith/  
Primary Examiner, Art Unit 1655  
August 5, 2009